APR 2 4 2002

K020954

Attachment 4

510(k) Summary

Device Description

Trade Names: H/S Catheter Procedure Tray
H/S Elliptosphere Procedure Tray
Multipurpose Procedure Tray

Common Name: Hysterosalpingography or Hysterosonography Trays (Product Code LKF)

Classification Name: Unclassified

Predicate Device

Ackrad H/S Procedure Tray K881680, 7/15/88

Date

April 23, 2002

Contact

Richard Hettenbach
Vice President, Regulatory Affairs and Quality Assurance
Ackrad Laboratories, Inc.
70 Jackson Drive
Cranford, NJ 07016
Tel: (908) 276-6390
Fax: (908) 276-1895

Device Description

The H/S Procedure Tray, Elliptosphere Procedure Tray and Multi-Purpose Tray contain components that can be used for conducting either Hysterosalpinography (examination of the uterus and fallopian tubes using x-rays) or Hysterosonography (examination of the uterus and falopian tubes using ultrasound sonography). All components are provided sterile for single use only.

Technological Characteristics	The expanded tray has the same technological characteristics as the predicate device. The intended use, operating principle, incorporate the same product designs incorporate the same materials and are packaged and sterilized using the same materials and processes.
Conclusion	The H/S Catheter Procedure Tray, H/S Elliptosphere Procedure Tray and Multi-Purpose Procedure Tray are substantially equivalent to the predicate H/S Procedure Tray.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2002

Mr. Richard Hettenbach
Vice President, Regulatory Affairs and Quality Assurance
Ackrad Laboratories
70 Jackson Drive
CRANFORD NJ 07016

Re: K020954
Trade Name: H/S Procedure Tray (5F and 7F), Model 61-5205 and 61-5207
H/S Elliptosphere procedure Tray, Model 61-4205
Multi-purpose Procedure Tray, Model 61-2000
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 LKF
Dated: March 13, 2002
Received: March 25, 2002

Dear Mr. Hettenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains providone-iodine ointment and providone-iodine solution which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Attachment 2

Indications for Use Statement

510(k) Number	K020954
Device Name	H/S Procedure Tray H/S Elliptosphere Procedure Tray Multipurpose Procedure Tray
Indications for Use	Procedure trays containing components intended for the delivery of diagnostic contrast media agents in the female reproductive tract for examination of the uterus and fallopian tubes (i.e. Hysterosalpingography or Hysterosonography).

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020954

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)